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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,095	01/07/2004	Bill E. Cham	P07389US01/BAS	2329
881	7590	11/09/2005	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			PESELEV, ELLI	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/752,095

Applicant(s)

CHAM, BILL E.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The disclosure is objected to because of the following informalities: the status of the parent application no. 09/958,333 has not been updated on page1 of the specification.

Appropriate correction is required.

Claims 29, 32, 50 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "an aqueous solvent" (claims 29 and 50) and "wherein a time period of at least about 7 days has elapsed between the extraction and removal steps" (claims 32 and 53) is not disclosed or suggested by the specification as originally filed.

Claims 1-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" (claims 24 and 43) renders the claims indefinite since it is not clear what is encompassed by said term i.e. the scope of the claimed invention cannot be determined. Note that the specification fails to provide a definition for said term. The use of the term "comprising" instead of "selected from" is improper in the Markush terminology "'X" is a radical selected from the group comprising" (claims 24 and 43).

Regarding claims 25 and 44, the phrase "eg" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Applicant's arguments filed June 25, 2004 have been fully considered but they are not persuasive.

Applicant contends that page 9 of the specification provides a definition for the term "derivative". However, page 9 of the specification provides description of the term "carbohydrate".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (Cancer Letters, 5 (1990) 221-225).

The claims are directed to a method of preparing a glycoalkaloid preparation which includes the step of removing essentially all free sugars derived from the glycoalkaloid, compositions produced by such methods and and method of treating cancer.

Claims 49-52 also include the step of removing any aglycone from the glycoalkaloid preparation.

Cham et al disclose a glycoalkaloid composition useful for treating cancer. Cham et al also disclose the free rhamnose inhibits the efficacy of a glycoalkaloid composition

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and that an aglycone is not effective against cancer (see, for example, page 221, last paragraph). Therefore, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to remove free sugars and aglycones from the a glycoalkaloid composition in order to improve its efficacy.

Applicant's arguments filed June 25, 2005 have been fully considered but they are not persuasive.

Applicant contends that Cham et al disclose addition of rhamnose to the glycoalkaloid preparation and does not disclose the inhibitory effect of the free sugars resulting from the degradation of the glycoalkaloids. This argument has not been found persuasive. Since rhamnose was known to have inhibitory effect on a glycoalkaloid preparation and aglycone was known to be ineffective in the treatment of cancer, a person having ordinary skill at the time the instant invention was made would have been motivated to remove sugars and aglycons from the glycoalkaloid preparation whether said sugars and aglycones are the result of degradation or addition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

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